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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,845	01/13/2006	Gael Lamoureux	TIP-0047-USPCT	2346

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EXAMINER	
BAEK, BONG-SOOK	
ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/564,845	LAMOUREUX ET AL.	
	Examiner	Art Unit	
	BONG-SOOK BAEK	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10 and 12-17* is/are pending in the application.

4a) Of the above claim(s) *1-9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10 and 12-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of claims

The amendment filed on January 29, 2009 is acknowledged. Claims 1-9 have been withdrawn and claim 11 has been cancelled. Claims 10 and 12-17 are under examination in the instant office action.

Applicants' arguments, filed on January 29, 2009, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application. Responses are limited to Applicants' arguments relevant to either reiterated or newly applied rejections.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 10 and 12-17 are rejected under 35 U.S.C. 103(a) as being obvious over US 6,027,747 (Issue date: 2/22/2000) in view of WO 01/22938 A1 (pub. Date: 4/5/2001). A copy of WO 0122938 A1 is not supplied because it is cited in the instant specification thus Applicants have a copy.

US 6,027,747 teaches a solid dispersion of at least one therapeutic agent preferably hardly water-soluble active ingredients such as antivirals in a hydrophilic carrier, made by the process comprising dissolving at least one therapeutic agent in a volatile organic solvent containing a very hydrophilic polymer and evaporating the solvent to dryness to form a co-precipitate of therapeutic agent and hydrophilic polymer (abstract and column 3, line 49-column 4, line 8) and this process provide a novel process for dry pharmaceutical products and the co-precipitate formed thereby which has faster and greater resorption when administered orally (column 2, lines 17-20). It further teaches that a surface-active agent such as non-ionic surface agent can be further added (column 3, lines 33-38). In the preferable examples, the amount of surface agent ranges from 0.5 to 20%, preferably 1-10% , related to the whole mass, which overlaps or falls within the claimed ranges in instant claims 12 and 15, and the weight ratio of the hydrophilic polymer (polyvinyl pyrrolidone) to the active ingredient (progesterone) ranges about 4:1 to 1:1 (column 5, lines 47-50 and tables I-III), which falls within the claimed range in the instant claim 14. US 6,027,747 teaches that for a pharmaceutical dosage form, the granules or the pellets are made of any carbohydrates (neutral hydrophilic carrier) such as starch, saccharose

dextrins or cellulose and the organic solution comprising a therapeutic agent and a hydrophilic polymer is sprayed thereon (column 6, lines 41-43). Furthermore, it teaches that the particle size of the samples for the galenical tests is lower than 100 μm (column 17, lines 65-67).

The reference differs from the instant invention insofar as it does not expressly teach specific species of antiviral agents such as antiviral pyrimidine or triazine. Also, it is silent about the inert hydrophilic carrier being present in an amount of up to 95% by weight.

WO 01/22938 A1 teaches a pharmaceutical composition containing an antiviral pyrimidine or a triazine compound, or their combination and one or more water-soluble (hydrophilic) polymers (abstract and p33, line 35-p34, line 3). It further teaches the pharmaceutical composition can be prepared as a solid dispersion by various techniques such as melt-extrusion, spray-drying and solution-evaporation (p37, lines 34-37) and the solid dispersion products is milled or ground to particles having a particle size of less than 1500 μm, preferably less than 400 μm, more preferably less than 250 μm and most preferably less than 125 μm (p39, lines 17-19).

It would have been prima facie obvious to one having ordinary skill in the art at the time of the invention was made to use any of the species of the genus of antiviral agents for making a particle as taught by US 6,027,747 because any such antiviral agent could have been used, including antiviral pyrimidine or triazine and furthermore, WO 01/22938 A1 teaches antiviral pyrimidine or triazine compound or its combination, which can be prepared as a particle of a solid dispersion.

In addition, one of ordinary skill in the art at the time of the invention was made would have reasoned that the inert hydrophilic carrier can not be present more than 95% by weight

since the particle should also contain the other ingredients including a therapeutic agent, a hydrophilic polymer, and a surface-active agent.

Response to Applicants' argument:

Applicants argued that '747 patent contains a laundry list of possible therapeutic agents and does not teach or suggest a particle comprising pyrimidine or triazine as claimed. Also, Applicants argues that WO01/22938, which discloses pharmaceutical compositions of antiviral compounds that comprises particles obtainable by melt-extrusion, spray-drying and solution-evaporation, also does not disclose or suggest the claimed invention. However, applicants did not provide any arguments regarding why the instant claims are not obvious over or suggested by the combination of two references.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

As stated in the previous action mailed on 10/2/2008, it would have been prima facie obvious to one having ordinary skill in the art at the time of the invention was made to apply the method of making a particle comprising a co-precipitate as taught by US 6,027,747 for other therapeutic agents such as antiviral pyrimidine or triazine because of the following reasons: US 6,027,747 already suggested that any antiviral agent can be used for making a particle comprising a co-precipitate. The reference further states that the disclosed process provide a novel process for dry pharmaceutical products and the co-precipitate formed thereby has faster and greater resorption when administered orally. Furthermore, WO 01/22938 A1 teaches that

antiviral pyrimidine or triazine compound or its combination can be prepared as a particle of a solid dispersion by spray drying or solution evaporation, which is a method to prepare co-precipitate (evidentiary reference: Vasconcelos *et al*, Drug Discovery Today, 12:1068-1075, 2007). Thus, one having ordinary skill in the art at the time of the invention was made would have been motivated to try to make a particle of a co-precipitate comprising antiviral pyrimidine or triazine taught by WO 01/22938 by using the method as taught by US 6,027,747 on the expectation of getting a pharmaceutical product with improved properties (improved resoprtion).

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BONG-SOOK BAEK whose telephone number is 571-270-5863. The examiner can normally be reached 9:00-6:00 Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian-Yong S Kwon/
Primary Examiner, Art Unit 1614
/Bbs/

BONG-SOOK BAEK
Examiner, Art Unit 1614